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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/526,690

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Matti Siren

18593

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20872 7590 06/17/2008  
MORRISON & FOERSTER LLP  
425 MARKET STREET  
SAN FRANCISCO, CA 94105-2482

EXAMINER

HELM, CARALYNNE E

ART UNIT

PAPER NUMBER

1615

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/526,690	<b>Applicant(s)</b> SIREN, MATTI	
	<b>Examiner</b> CARALYNNE HELM	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 10 and 13-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION*****Election/Restrictions***

Applicant's election of Group 1 and the species D-3,4,5-tri-O-(phenylcarbamoyl)myoinositol-1,2,6-triphosphate in the reply filed on April 16, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). The restriction requirement is deemed proper and thereby made FINAL.

Applicant's original claim set contained "use" claims which were separately interpreted as a product or a process, thus their inclusion in both a product and process group in the restriction requirement. A lack of unity between the product and the process was demonstrated so applicant is afforded prosecution of the product or the process at this time. Applicant elected the group drawn to a product; however, only one of the original "use" claims (claims 10) was amended into a product claim. The remaining use claims (claims 13-16) were amended into process claims and thus became part of the non-elected group. Therefore claims 10 and 12-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites that the set of substituents  $R^1$  to  $R^{11}$  *are* the options presented by listings i, ii, iii, iv, *and* v. Since the R groups are given distinct designations/superscripts it appears that they could all be different chemical moieties, however the phrasing that uses the term “are” says that they are all the same chemical moiety. Thus the collection of structures being claimed is not clear. Furthermore, the R groups are each also claimed to be five different chemical moieties simultaneously ( $R^1$  to  $R^{11}$  *are* the options presented by listings i, ii, iii, iv, *and* v) as opposed to a single chemical moiety ( $R^1$  to  $R^{11}$  *are* the options presented by listings i, ii, iii, iv, *or* v) as likely intended.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites that the set of substituents  $V^1$  and  $V^2$  *are* a series of chemical moieties. Since the V groups are given distinct designations/superscripts it appears that they could all be different chemical moieties, however the phrasing that uses the term “are” says that they are all the same chemical moiety. Thus the collection of structures being claimed is not clear. Furthermore, the V groups are each also claimed to be eighty-four different chemical moieties simultaneously ( $V^1$  to  $V^2$  *are* the options presented by OH, (CH<sub>2</sub>)OH,...,CF<sub>2</sub>COOH) as opposed to a single chemical moiety ( $V^1$  to  $V^2$  *are* the options presented by OH, (CH<sub>2</sub>)OH,... *or*, CF<sub>2</sub>COOH) as likely intended.

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Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 7 recites the broad recitation "4 to 24 atoms", and the claim also recites "5 to 8 atoms" which is the narrower statement of the range/limitation.

For the purposes of applying prior art, claim 2 is interpreted such that R<sup>1</sup> to R<sup>11</sup> are the same chemical moiety selected from group i, ii, iii, iv, or v, who have substitutions with 0-6 of the recited additional chemical moieties; claim 3 is interpreted such that V<sup>1</sup> and V<sup>2</sup> are the same chemical moiety selected from the recited group in the alternative (OH, (CH<sub>2</sub>)OH,... or, CF<sub>2</sub>COOH); and claim 7 is interpreted such that the cyclic moiety comprises 4 to 24 atoms.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Persson et al. (U.S. Patent No. 5,866,557) in view of Chudzik et al. (U.S. PGPub No. 2002/0032434).

Persson et al. teach a collection of inositoltriphosphate compounds that are used to treat inflammatory conditions (see title and abstract). Persson et al. go on to teach particular pathologies, including inflammatory conditions caused by injuries due to or following surgery and operations with grafts and catheters, that the taught compounds are envisioned to treat as well as generally teach that the compounds are effective against conditions in which inflammation occurs (see column 1 lines 58-62 and column 2 lines 1-3; instant claim 1). Further, Persson et al. specifically teach D-3,4,5-tri-O-(phenylcarbamoyl)myoinositol-1,2,6-triphosphate as a particularly envisioned compound in the invention (see example 5; instant claims 1-9). Persson et al. do not specifically teach the incorporation of their compounds into a stent coating.

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Chudzik et al. teach a stent coated with a mixture of polymer and a bioactive agent to counteract the restenosis and inflammation that occurs when the device is placed in the body (see paragraph 3, 17, 28 and claim 21). In particular, Chudzik et al. teach anti-inflammatory compounds as bioactive agents to include in the stent coating (see paragraph 25 lines 12-13). Since the particular compounds of Persson et al. are taught to be useful in ameliorating inflammation in general and when due to or after surgeries that involve the use of grafts (stent) or catheters, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use their taught D-3,4,5-tri-O-(phenylcarbamoyl)myoinositol-1,2,6-triphosphate in the stent coating of Chudzik et al. Therefore claims 1-9 are obvious over Persson et al. in view of Chudzik et al.

Claims 1-3 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Persson et al. in view of Chudzik et al. as applied to claims 1-9 above, and further in view of Shvets (Russian Chemical Reviews 1974 43:488-502).

Persson et al. in view of Chudzik et al. make obvious a stent coated with D-3,4,5-tri-O-(phenylcarbamoyl)myoinositol-1,2,6-triphosphate (see instant claims 1-3). This modified reference does not teach that the phosphate groups are positioned such that one is axial and two are equatorial in this compound.

Shvets teaches the stereochemistry of myoinositol derivatives and that the most stable conformational form of myoinositol has one axial hydroxyl group at the 2 position and the remaining hydroxyl groups placed equatorial (see page 88 column 2 paragraph 1 lines 1-6; instant claim 11). The same stereochemistry is taught for phosphated versions of the compound (see page 496 scheme 16; instant claim 11). It is therefore the examiner's position that based upon the teachings of Shvets, D-3,4,5-tri-O-(phenylcarbamoyl)myoinositol-1,2,6-triphosphate

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would have its phosphate groups located such that two were equatorial and one was axial. Therefore claims 1-3 and 11 are obvious over Persson et al. in view of Chudzik et al. and Shvets.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is (571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MP WOODWARD/  
Supervisory Patent Examiner, Art Unit 1615

/Caralynne Helm/  
Examiner, Art Unit 1615